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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/650,055	08/29/2000	Robert A. Kay	1040-5	8753

23869 7590 09/10/2003

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EXAMINER
JONES, DWAYNE C

ART UNIT	PAPER NUMBER
1614	10

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/650,055	Applicant(s) KAY ET AL.	
	Examiner Dwayne C Jones	Art Unit 1614	

-- The MAILING DATE of this c mmunication appears n the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2003 and 23 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Claims

1. Claims 1-5 and 7-48 are pending.

2. Claims 1-5 and 7-48 are rejected.

3. Prosecution on the merits of this application is reopened on claims 1-5 and 7-48 considered unpatentable for the reasons indicated below under the section entitled Response to Arguments.

Response to Arguments

4. Applicant's arguments filed January 23, 2003 have been fully considered but they are not persuasive. Applicants make the following arguments. First, applicants argue that Murch et al. relates to a composition and method for treating inflammatory bowel disease. Second, applicants allege that the instant invention does not teach or suggest and enteric coasting as does the prior art reference of Murch et al. Applicants also argue that Henderson et al. and Shell do not contain a controlled-release component. Furthermore, applicant alleges that McClain et al. do not teach or even suggest methods or compositions for controlling the rate of glucosamine administration to avoid an insulin resistance response.

5. Applicants first argue that Murch et al. relates to a composition and method for treating inflammatory bowel disease. The fact that Murch et al. is directed to a method of treating a different disease is irrelevant to the instant composition claims 1-5, 16, 17, and 27-34 because the above-stated claims are composition claims, which happened to

include an intended use. The prior art reference of Murch et al. do teach of a controlled or time-released composition of N-acetylglucosamine with a variety of time-release substances, namely cellulose derivatives, (see column 3, lines 15, 20, and 22). In addition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

6. Responding to applicants allegation that the instant invention does not teach or suggest and enteric coasting as does the prior art reference of Murch et al., it is again pointed out that claims 1-5, 16, 17 and 27-34 are composition claims that have an intended use recitation and functional language. Accordingly, Murch et al. do teach of a controlled-release composition of N-acetylglucosamine that contains a time-release substance of a cellulose derivative. Moreover, applicants recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

7. Applicants next argue that Henderson et al. and Shell do not contain a controlled-release component. This argument is not found persuasive because the instant rejection is over the combination of Henderson et al. in view of Shell and in further view

of McClain et al. prior art references. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Henderson teaches of the administration of glucosamine for treatment, prevention and repair of connective tissue, namely arthritis, joint inflammation; Shell discloses of sustained-release oral dosages forms that contain an active agent that is dispersed in alkyl cellulose, such as hydroxyethylcellulose or hydroxypropylcellulose; and McClain et al. also disclose that excess hexosamine flux causes resistance to insulin. Accordingly, the rejection of Henderson et al. in view of Shell and in further view of McClain et al. do disclose of the controlled-release compositions containing glucosamine and its derivatives.

8. Furthermore, applicant alleges that McClain et al. do not teach or even suggest methods or compositions for controlling the rate of glucosamine administration to avoid an insulin resistance response. McClain et al. specifically teach that glucose is an important regulator of metabolism and abnormal concentrations of glucose are likely to cause some adverse effects due to hyperglycemia, including insulin resistance. In particular, McClain et al. teach that there is evidence of hexosamine flux causes insulin resistance, (see abstract). McClain et al. also disclose that an altered relationship involving glucose homeostasis in non-insulin dependent diabetes mellitus might

contribute to the underlying cause of insulin resistance, (see page 1007, column 2, last paragraph).

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1-5, 16, 17, and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murch et al. of U.S. Patent No. 6,046,179. Murch et al. teach of a time-released composition of N-acetylglucosamine with cellulose or hydrophilic polymers, (see abstract and columns 2 and 3). Although the prior art reference of Murch et al. is directed to N-acetylglucosamine vice glucosamine, it would have been obvious to the skilled artisan to easily obtain a sustained-release composition of glucosamine, in view of Murch et al., by easily removing the acetyl group from position No. 2 of the glucose moiety.

11. Claims 1-5 and 7-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. of U.S. Patent No. 5,364,845 in view of Shell of U.S. Patent No. 5,582,837 in further view of McClain et al. Henderson teaches of the administration of glucosamine for treatment, prevention and repair of connective tissue, namely arthritis, joint inflammation, (see column 1, lines 15-23 and column 4, lines 28-29, and claims 1-18). Shell discloses of sustained-release oral dosages forms that contain an active agent that is dispersed in alkyl cellulose, such as hydroxyethylcellulose or hydroxypropylcellulose, (see abstract and claims 1 and 2). In addition, Shell provides

motivation to the skilled artisan to administer pharmaceuticals and nutraceuticals to (1) reduce side effects from the pharmaceutical and (2) to administer the pharmaceutical less frequently, (see column 3). McClain et al. teach that glucose is an important regulator of cell growth and metabolism, and that adverse effects of hyperglycemia are reflections of normal regulation by abnormal concentrations of glucose. McClain et al. also teach that the hexosamine biosynthesis pathway regulates the uptake of glucose, synthesis of glycogen and glycolysis. McClain et al. also disclose that excess hexosamine flux causes resistance to insulin, (see abstract and entire article). McClain et al. specifically teach that glucose is an important regulator of metabolism and abnormal concentrations of glucose are likely to cause some adverse effects due to hyperglycemia, including insulin resistance. McClain et al. also disclose that an altered relationship involving glucose homeostasis in non-insulin dependent diabetes mellitus might contribute to the underlying cause of insulin resistance, (see page 1007, column 2, last paragraph). The determination of a dosage and modes of administration, which have the optimum therapeutic index is well within the purview of the skilled artisan. Accordingly, the artisan would be motivated to determine optimum amounts and modes of administration in order to get the maximum effect of the drug. In addition, Shell provides motivation to the skilled artisan to administer pharmaceuticals and nutraceuticals to (1) reduce side effects from the pharmaceutical and (2) to administer the pharmaceutical less frequently, (see column 3). For these reasons, the administration of the nutraceutical of glucosamine could be administered and a sustained-release method so that the hexosamine biosynthesis pathway is not

compromised. These prior art references provide the skilled artisan with the neccessesary motivation to control hyperglycemia and insulin resistance with the manipulation of the hexosamine biosynthesis pathway via the controlled administration of glucosamine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. C. JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
September 5, 2003